

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

NIPPON SHINYAKU CO., LTD.,)	
Plaintiff,)	
)	
v.)	
)	
SAREPTA THERAPEUTICS, INC.,)	
)	
Defendant.)	C.A. No. 21-1015-MN
SAREPTA THERAPEUTICS, INC.,)	DEMAND FOR JURY TRIAL
Defendant and Counter-Plaintiff,)	
)	
v.)	
)	
NIPPON SHINYAKU CO., LTD. and)	
NS PHARMA, INC.)	
)	
Plaintiff and Counter-Defendants.)	

SCHEDULING ORDER

This **16th** day of **August 2022**, ~~the Court having waived an initial Rule 16(b) scheduling~~ MN
~~conference pursuant to Local Rule 16.1(b), and~~ the parties having determined after discussion that
the matter cannot be resolved at this juncture by settlement, voluntary mediation, or
binding arbitration;

IT IS HEREBY ORDERED that:

1. Rule 26(a)(1) Initial Disclosures and E-Discovery Default Standard.

Unless otherwise agreed to by the parties, the parties shall make their initial disclosures pursuant to Federal Rule of Civil Procedure 26(a)(1) **within fourteen (14) days** of the date this Order is entered by the Court. If they have not already done so, the parties are to review the Court's Default Standard for Discovery, Including Discovery of Electronically Stored Information

(“ESI”), which is posted at <http://www.ded.uscourts.gov> (*see* Other Resources, Default Standard for Discovery) and is incorporated herein by reference.

2. Joinder of Other Parties and Amendment of Pleadings. All motions to join other parties, and to amend or supplement the pleadings, shall be filed on or before **March 23, 2023**. Unless otherwise ordered by the Court, any motion to join a party or motion to amend the pleadings shall be made pursuant to the procedures set forth in Paragraphs 8(g) and 9.

3. Application to Court for Protective Order. Should counsel find it will be necessary to apply to the Court for a protective order specifying terms and conditions for the disclosure of confidential information, counsel should confer and attempt to reach an agreement on a proposed form of order and submit it to the Court **within thirty (30) days** from the date the Court enters this Order. Should counsel be unable to reach an agreement on a proposed form of order, counsel must follow the provisions of Paragraph 8(g) below.

Any proposed protective order must include the following paragraph:

Other Proceedings. By entering this order and limiting the disclosure of information in this case, the Court does not intend to preclude another court from finding that information may be relevant and subject to disclosure in another case. Any person or party subject to this order who becomes subject to a motion to disclose another party’s information designated “confidential” [the parties should list any other level of designation, such as “highly confidential,” which may be provided for in the protective order] pursuant to this order shall promptly notify that party of the motion so that the party may have an opportunity to appear and be heard on whether that information should be disclosed.

4. Papers Filed Under Seal. In accordance with section G of the Revised Administrative Procedures Governing Filing and Service by Electronic Means, a redacted version of any sealed document shall be filed electronically within seven (7) days of the filing of the sealed document.

5. Courtesy Copies. The parties shall provide to the Court two (2) courtesy copies of all briefs and any other document filed in support of any briefs (*i.e.*, appendices, exhibits, declarations, affidavits etc.). This provision also applies to papers filed under seal. All courtesy copies shall be double-sided.

6. ADR Process. Pursuant to Standing Order No. 2022-2, this matter shall not be referred to a magistrate judge to explore the possibility of alternative dispute resolution. The Parties may request an ADR referral at an appropriate time.

7. Absent agreement among the parties, and approval of the Court:

(a) By **April 18, 2022**, Plaintiff and Counterclaim-Plaintiff shall identify the accused product(s), including accused methods and systems, and its damages model, as well as the asserted patent(s) that the accused product(s) allegedly infringe(s). Plaintiff and Counterclaim-Plaintiff shall also produce the file history for each asserted patent.

(b) By **May 18, 2022**, Defendant and Counterclaim-Defendants shall produce core technical documents related to the accused product(s), sufficient to show how the accused product(s) work(s), including but not limited to non-publicly available operation manuals, product literature, schematics, and specifications. Defendant and Counterclaim-Defendants shall also produce sales figures for the accused product(s).

(c) By **June 17, 2022**, Plaintiff and Counterclaim-Plaintiff shall produce an initial claim chart relating each known accused product to the asserted claims each such product allegedly infringes.

(d) By **July 18, 2022**, Defendant and Counterclaim-Defendants shall produce its initial invalidity contentions for each asserted claim, as well as the known related invalidating references.

(e) By **February 24, 2023**, Plaintiff and Counterclaim-Plaintiff shall provide final infringement contentions.

(f) By **March 3, 2023**, Defendant and Counterclaim-Defendants shall provide final invalidity contentions.

(g) By **March 3, 2023**, Defendant and Counterclaim-Defendants shall provide final non-infringement contentions.

(h) By **March 10, 2023**, Plaintiff and Counterclaim-Plaintiff shall provide final validity contentions.

8. Discovery. Unless otherwise ordered by the Court or agreed to by parties, the limitations on discovery set forth in the Federal Rules shall be strictly observed.

(a) Fact Discovery Cut Off. All fact discovery in this case shall be initiated so that it will be completed on or before **May 25, 2023**.

(b) Document Production. Document production shall be substantially complete by **January 20, 2023**.

(c) Requests for Admission. A maximum of **60** requests for admission are permitted for each side. Requests for Admission that are limited only to authentication of documents shall not be counted against this limit.

(d) Interrogatories.

i. A maximum of **35** interrogatories, including contention interrogatories, are permitted for each side.

ii. The Court encourages the parties to serve and respond to contention interrogatories early in the case. In the absence of agreement among the parties, contention interrogatories, if filed, shall first be addressed by the party with the burden of proof. The adequacy

of all interrogatory answers shall be judged by the level of detail each party provides (*i.e.*, the more detail a party provides, the more detail a party shall receive).

(e) Depositions.

i. Limitation on Hours for Deposition Discovery. Each side is limited to a total of **100** hours of taking testimony by deposition upon oral examination. For any witness who testifies in a foreign language with an interpreter, each two hours of deposition testimony shall be counted as **one hour and 15 minutes**.

ii. Location of Depositions. Any party or representative (officer, director, or managing agent) of a party filing a civil action in this district court must ordinarily be required, upon request, to submit to a deposition at a place designated within this district. Exceptions to this general rule may be made by order of the Court. A defendant who becomes a counterclaimant, cross-claimant, or third-party plaintiff shall be considered as having filed an action in this Court for the purpose of this provision. The parties will meet and confer about any restrictions on the location and procedures for depositions in view of the COVID pandemic and travel conditions.

(f) Disclosure of Expert Testimony.

i. Expert Reports. For the party who has the initial burden of proof on the subject matter, the initial Federal Rule of Civil Procedure 26(a)(2) disclosure of expert testimony is due on or before **August 14, 2023**. The supplemental disclosure to contradict or rebut evidence on the same matter identified by another party is due on or before **September 11, 2023**. Reply expert reports from the party with the initial burden of proof are due on or before **October 2, 2023**. No other expert reports will be permitted without either the consent of all parties or leave

of the Court. Along with the submissions of the expert reports, the parties shall advise of the dates and times of their experts' availability for deposition.

ii. Expert Report Supplementation. The parties agree they **will** permit expert declarations to be filed in connection with motions briefing (including case-dispositive motions).

iii. Objections to Expert Testimony. To the extent any objection to expert testimony is made pursuant to the principles announced in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), as incorporated in Federal Rule of Evidence 702, it shall be made by motion **no later than the deadline for dispositive motions set forth herein**, unless otherwise ordered by the Court. Briefing will be presented pursuant to the Court's Local Rules.

iv. Expert Discovery Cut Off. All expert discovery in this case shall be initiated so that it will be completed on or before **October 30, 2023**.

(g) Discovery Matters and Disputes Relating to Protective Orders.

i. Any discovery motion filed without first complying with the following procedures will be denied without prejudice to renew pursuant to these procedures.

ii. Should counsel find, after a reasonable effort pursuant to Local Rule 7.1.1. that they are unable to resolve a discovery matter or a dispute relating to a protective order, the parties involved in the discovery matter or protective order dispute shall contact the Court's Judicial Administrator to schedule an argument.

iii. On a date to be set by separate order, generally not less than four (4) days prior to the conference, the party seeking relief shall file with the Court a letter, not to exceed three (3) pages, outlining the issues in dispute and its position on those issues. On a date to be set

by separate order, but generally not less than three (3) days prior to the conference, any party opposing the application for relief may file a letter, not to exceed three (3) pages, outlining that party's reasons for its opposition.

iv. The parties shall provide to the Court two (2) courtesy copies of its discovery letter and any other document filed in support of any letter (*i.e.*, appendices, exhibits, declarations, affidavits etc.). This provision also applies to papers filed under seal. All courtesy copies shall be double-sided.

v. Should the Court find further briefing necessary upon conclusion of the conference, the Court will order it. Alternatively, the Court may choose to resolve the dispute prior to the conference and will, in that event, cancel the conference.

9. Motions to Amend / Motions to Strike.

(a) Any motion to amend (including a motion for leave to amend) a pleading or any motion to strike any pleading or other document shall be made pursuant to the discovery dispute procedure set forth in Paragraph 8(g) above.

(b) Any such motion shall attach the proposed amended pleading as well as a "redline" comparison to the prior pleading or attach the document to be stricken.

10. Technology Tutorials. Although technology tutorials are not required by the Court, they are appreciated and, if any party chooses to file such a tutorial, it shall be submitted on or before the date that the Joint Claim Construction Brief is filed.

11. Claim Construction Issue Identification. On **October 26, 2022**, the parties shall exchange a list of those claim term(s)/phrase(s) that they believe need construction and their proposed claim construction of those term(s)/phrase(s). This document will not be filed with the Court. Subsequent to exchanging that list, the parties will meet and confer to prepare a Joint Claim

Construction Chart to be submitted two weeks prior to service of the opening claim construction brief. The parties' Joint Claim Construction Chart should identify for the Court the term(s)/phrase(s) of the claim(s) in issue, and should include each party's proposed construction of the disputed claim language with citation(s) only to the intrinsic evidence in support of their respective proposed constructions. Intrinsic evidence (including copies of the patent(s) at issue) shall NOT be attached to the joint claim construction chart and, instead, the parties shall include a joint appendix with the joint claim construction brief, and the joint appendix shall include a copy of the patent(s) at issue and portions of all relevant intrinsic evidence that would have otherwise been included with the joint claim construction chart, as well as any additional evidence cited in the parties' briefing.

12. Claim Construction Briefing. Plaintiff and Counterclaim-Plaintiff shall serve, but not file, their opening briefs with respect to their asserted patents, not to exceed 20 pages, on **March 31, 2023**. Defendant and Counterclaim-Defendants shall serve, but not file, their answering briefs, not to exceed 30 pages, on **April 18, 2023**. Plaintiff and Counterclaim-Plaintiff shall serve, but not file, reply briefs, not to exceed 20 pages, on **May 5, 2023**. Defendant and Counterclaim-Defendants shall serve, but not file, their sur-reply briefs, not to exceed 10 pages, on **May 15, 2023**. No later than **May 22, 2023**, the parties shall file the Joint Claim Construction Briefs. The parties shall copy and paste their unfiled briefs into one brief, with their positions on each claim term in sequential order, in substantially the form below. If a joint brief as submitted is more than 80 pages, the parties must certify that the page limits (or equivalent word counts) in the Scheduling Order have been complied with and provide a brief explanation (e.g., formatting issues, listing of agreed-upon terms) as to why the brief is longer than 80 pages.

JOINT CLAIM CONSTRUCTION BRIEF

I. Agreed-Upon Constructions

II. Disputed Constructions

[TERM 1]

1. Plaintiff's (Or Counterclaim-Plaintiff's) Opening Position
2. Defendant's (Or Counterclaim-Defendants's) Answering Position
3. Plaintiff's (Or Counterclaim-Plaintiff's) Reply Position
4. Defendant's (Or Counterclaim-Defendants's) Sur-Reply Position

[TERM 2]

1. Plaintiff's (Or Counterclaim-Plaintiff's) Opening Position
2. Defendant's (Or Counterclaim-Defendants's) Answering Position
3. Plaintiff's (Or Counterclaim-Plaintiff's) Reply Position
4. Defendant's (Or Counterclaim-Defendants's) Sur-Reply Position

The parties need not include any general summaries of the law relating to claim construction. If there are any materials that would be submitted in an index, the parties shall submit them in a Joint Appendix.

13. Hearing on Claim Construction. Beginning at **10:00 a.m.** on **June 29, 2023**, the Court will hear argument on claim construction. The parties need not include any general summaries of the law relating to claim construction in their presentations to the Court. The parties shall notify the Court, by joint letter submission, no later than the date on which their joint claim construction brief is filed: (i) whether they request leave to present testimony at the hearing; and (ii) the amount of time they are requesting be allocated to them for the hearing.

Provided that the parties comply with all portions of this Scheduling Order, and any other orders of the Court, the parties should anticipate that the Court will issue its claim construction order within sixty (60) days of the conclusion of the claim construction hearing. If the Court is

unable to meet this goal, it will advise the parties no later than sixty (60) days after the conclusion of the claim construction hearing.

14. Supplementation. Absent agreement among the parties, and approval of the Court, no later than **February 24, 2023 and March 3, 2023, respectively** the parties must finally supplement, *inter alia*, the identification of all accused products and of all invalidity references.

15. Case Dispositive Motions.

(a) All case dispositive motions, an opening brief, and affidavits, if any, in support of the motion shall be served and filed on or before **November 20, 2023**. Answering case dispositive briefs shall be served and filed by **December 15, 2023** and reply case dispositive briefs shall be served and filed by **January 10, 2024**. No case dispositive motion under Rule 56 may be filed more than ten (10) days before the above date without leave of the Court.

(b) Concise Statement of Facts Requirement. Any motion for summary judgment shall be accompanied by a separate concise statement, not to exceed six (6) pages, which details each material fact which the moving party contends is essential for the Court's resolution of the summary judgment motion (not the entire case) and as to which the moving party contends there is no genuine issue to be tried. Each fact shall be set forth in a separate numbered paragraph and shall be supported by specific citation(s) to the record.

Any party opposing the motion shall include with its opposing papers a response to the moving party's concise statement, not to exceed six (6) pages, which admits or disputes the facts set forth in the moving party's concise statement on a paragraph-by-paragraph basis. To the extent a fact is disputed, the basis of the dispute shall be supported by specific citation(s) to the record. Failure to respond to a fact presented in the moving party's concise statement of facts shall indicate that fact is not in dispute for purposes of summary judgment. The party opposing the

motion may also include with its opposing papers a separate concise statement, not to exceed four (4) pages, which sets forth material facts as to which the opposing party contends there is a genuine issue to be tried. Each fact asserted by the opposing party shall also be set forth in a separate numbered paragraph and shall be supported by specific citation(s) to the record.

The moving party shall include with its reply papers a response to the opposing party's concise statement of facts, not to exceed four (4) pages, on a paragraph-by-paragraph basis. Failure to respond to a fact presented in the opposing party's concise statement of facts shall indicate that fact remains in dispute for purposes of summary judgment.

(c) Page limits combined with Daubert motion page limits. Each party is permitted to file as many case dispositive motions as desired provided, however, that each ***SIDE*** will be limited to a combined total of 40 pages for all opening briefs, a combined total of 40 pages for all answering briefs, and a combined total of 20 pages for all reply briefs regardless of the number of case dispositive motions that are filed. In the event that a party files, in addition to a case dispositive motion, a Daubert motion to exclude or preclude all or any portion of an expert's testimony, the total amount of pages permitted for all case dispositive and Daubert motions shall be increased to 50 pages for all opening briefs, 50 pages for all answering briefs, and 25 pages for all reply briefs for each ***SIDE***.¹

16. Applications by Motion. Except as otherwise specified herein, any application to the Court shall be by written motion filed with the Clerk. Any non-dispositive motion should contain the statement required by Local Rule 7.1.1.

¹ The parties must work together to ensure that the Court receives no more than a total of 250 pages (*i.e.*, 50 + 50 + 25 regarding one side's motions, and 50 + 50 + 25 regarding the other side's motions) of briefing on all case dispositive motions and *Daubert* motions that are covered by this scheduling order and any other scheduling order entered in any related case that is proceeding on a consolidated or coordinated pretrial schedule.

17. Motions in Limine. Motions *in limine* shall not be separately filed. All *in limine* requests and responses thereto shall be set forth in the proposed pretrial order. Each ***SIDE*** shall be limited to three (3) *in limine* requests, unless otherwise permitted by the Court. The *in limine* request and any response shall contain the authorities relied upon; each *in limine* request may be supported by a maximum of three (3) pages of argument, may be opposed by a maximum of three (3) pages of argument, and the side making the *in limine* request may add a maximum of one (1) additional page in reply in support of its request. If more than one party is supporting or opposing an *in limine* request, such support or opposition shall be combined in a single three (3) page submission (and, if the moving party, a single one (1) page reply), unless otherwise ordered by the Court. No separate briefing shall be submitted on *in limine* requests, unless otherwise permitted by the Court.

18. Pretrial Conference. On **May 6, 2024**, the Court will hold a pretrial conference in Court with counsel beginning at **4:30 p.m.** Unless otherwise ordered by the Court, the parties should assume that filing the pretrial order satisfies the pretrial disclosure requirement of Federal Rule of Civil Procedure 26(a)(3). The parties shall file with the Court the joint proposed final pretrial order in compliance with Local Rule 16.3(c) and the Court's Preferences and Procedures for Civil Cases not later than seven (7) days before the pretrial conference. Unless otherwise ordered by the Court, the parties shall comply with the timeframes set forth in Local Rule 16.3(d)(1)-(3) for the preparation of the joint proposed final pretrial order.

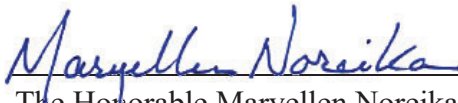
The parties shall provide the Court two (2) double-sided courtesy copies of the joint proposed final pretrial order and all attachments. The proposed final pretrial order shall contain a table of contents and the paragraphs shall be numbered.

19. Jury Instructions, Voir Dire, and Special Verdict Forms. Where a case is to be tried to a jury, pursuant to Local Rules 47.1(a)(2) and 51.1 the parties should file (i) proposed voir dire, (ii) preliminary jury instructions, (iii) final jury instructions, and (iv) special verdict forms seven (7) days before the final pretrial conference. This submission shall be accompanied by a courtesy copy containing electronic files of these documents, in Microsoft Word format, which may be submitted by e-mail to mn_civil@ded.uscourts.gov.

20. Trial. This matter is scheduled for a 10 day* jury trial beginning at 9:30 a.m. on **May 13, 2024** with the subsequent trial days beginning at 9:00 a.m. Until the case is submitted to the jury for deliberations, the jury will be excused each day at 4:30 p.m. The trial will be timed, as counsel will be allocated a total number of hours in which to present their respective cases.

21. Judgment on Verdict and Post-Trial Status Report. Within seven (7) days after a jury returns a verdict in any portion of a jury trial, the parties shall jointly submit a form of order to enter judgment on the verdict. At the same time, the parties shall submit a joint status report, indicating among other things how the case should proceed and listing any post-trial motions each party intends to file.

22. Post-Trial Briefing. Post-Trial Motions. Unless otherwise ordered by the Court, all SIDES are limited to a maximum of 20 pages of opening briefs, 20 pages of answering briefs, and 10 pages of reply briefs relating to any post-trial motions filed by that side, no matter how many such motions are filed.



The Honorable Maryellen Noreika
United States District Judge

*** Although the Court is setting aside 10 days for this jury trial, the actual number of trial days will be determined closer to trial.**

CHART OF RELEVANT DATES

EVENT	DEADLINE
Rule 26(a)(1) Initial Disclosures (¶ 1)	14 days from entry of Scheduling Order
Default Standard Paragraph 3 Initial Disclosures (¶ 1)	30 days from entry of Scheduling Order
Filing of Joint Proposed Protective Order (¶ 3)	30 days from entry of Scheduling Order
Plaintiffs & Counterclaim Plaintiff to Identify Accused Products (¶ 7a)	April 18, 2022
Defendant & Counterclaim-Defendants to Produce Core Technical Documents (¶ 7b)	May 18, 2022
Plaintiffs & Counterclaim-Plaintiffs to Provide Initial Claim Charts (¶ 7c)	June 17, 2022
Defendant & Counterclaim-Defendants to Provide Initial Invalidity Contentions (¶ 7d)	July 18, 2022
Exchange List of Claim Term(s)/Phrase(s) (¶ 11)	October 26, 2022
Substantial Completion of Document Production (¶ 8b)	January 20, 2023
Deadline for Plaintiffs & Counterclaim-Plaintiff to Supplement Identification of All Accused Products	February 24, 2023
Plaintiffs & Counterclaim Plaintiff to Provide Final Infringement Contentions (¶ 7e)	February 24, 2023
Deadline for Defendants & Counterclaim-Defendants to Supplement Invalidity References (¶ 14)	March 3, 2023
Defendant & Counterclaim-Defendants to Provide Final Invalidity Contentions (¶ 7f)	March 3, 2023
Defendant & Counterclaim-Defendants to Provide Final Non-Infringement Contentions (¶ 7g)	March 3, 2023
Plaintiff & Counterclaim-Plaintiff to Provide Final Validity Contentions (¶ 7h)	March 10, 2023
Filing of Joint Claim Construction Chart (¶ 11)	March 17, 2023
Last Day to Join Other Parties and to Amend the Pleadings (¶ 2)	March 23, 2023
Plaintiffs' Opening Claim Construction Brief & Counter-Claim Plaintiffs' Opening Claim Construction Brief (¶ 12)	March 31, 2023

EVENT	DEADLINE
Defendants' Answering Claim Construction Brief & Counterclaim-Claim Defendants' Answering Claim Construction Brief (¶ 12)	April 18, 2023
Plaintiffs' Reply Claim Construction Brief & Counterclaim-Plaintiffs' Reply Claim Construction Brief (¶ 12)	May 5, 2023
Defendant's Sur-Reply Claim Construction Brief & Counterclaim-Defendants' Reply Claim Construction Brief (¶ 12)	May 15, 2023
Filing of Joint Claim Construction Briefs (¶ 12)	May 22, 2023
Deadline to Submit Technology Tutorial (¶ 10)	May 22, 2023
Deadline to Request Leave to Present Testimony at Claim Construction Hearing and Inform Court of Time Needed for Hearing (¶ 13)	May 22, 2023
Fact Discovery Cut Off (¶ 8a)	May 25, 2023
Claim Construction Hearing (¶ 13)	June 29, 2023 at 10:00 a.m.
Opening Expert Reports (¶ 8f)	August 14, 2023
Rebuttal Expert Reports (¶ 8f)	September 11, 2023
Reply Expert Reports (¶ 8f)	October 2, 2023
Close of Expert Discovery (¶ 8f)	October 30, 2023
Case Dispositive Motions (Opening Briefs) (¶15(a))	November 20, 2023
Answering Case Dispositive Briefs (¶15(a))	December 15, 2023
Reply Case Dispositive Briefs (¶15(a))	January 10, 2024
Deadline to File Proposed Voir Dire, Preliminary Jury Instructions, and Final Jury Instructions (¶ 19)	7 days before Pretrial Conference
Deadline to File Joint Proposed Final Pretrial Order (¶ 18)	7 days before Pretrial Conference
Pretrial Conference (¶ 18)	May 6, 2024 at 4:30 p.m.
Trial (10-day jury)* (¶ 20)	May 13, 2024

* Although the Court is setting aside 10 days for this jury trial, the actual number of trial days will be determined closer to trial.